K031029

JUN 1 9 2003

510(k) Summary

ArthroCare Corporation
ArthroCare® Bipolar Loop Electrosurgery System

General Information

Submitter Name/Address:	ArthroCare Corporation 680 Vaqueros Avenue Sunnyvale, CA 94085-2936
Phone Number:	(408) 736-0224
Contact Person:	Valerie Defiesta-Ng Director, Regulatory Affairs
Date Prepared:	March 31, 2003

Device Description

Trade Name:	ArthroCare Bipolar Loop Electrosurgery System
Generic/Common Name:	Electrosurgical Device and Accessories
Classification Name:	Electrosurgical Cutting and Coagulation Device and Accessories (21 CFR 878.4400)

Predicate Devices

ArthroCare Bipolar Loop Electrosurgery System	K955531, K010568, K020832 and K022543
PlasmaKinetic Endourology Generator	K003569

Product Description

The ArthroCare Bipolar Loop Electrosurgery System is a bipolar, high frequency electrosurgical system consisting of three components: an electrosurgical generator called the Controller; a disposable, bipolar, single use Loop Electrode; and a reusable Patient Cable.

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Intended Uses

The ArthroCare Bipolar Loop Electrosurgery System is a bipolar electrosurgical device intended for use in patients requiring endoscopic surgery for general urological procedures. Urological tissue can be resected using this System, such as the prostate, in procedures including transurethral prostatectomy (TURP) and transurethral incisions in the prostate (TUIP), as well as tumors of the bladder wall. The System has been shown to be effective in tissue resection, ablation, and excision, as well as in hemostasis of blood vessels. It is intended for endoscopic procedures using saline solution, Ringer's lactate, or other conductive solutions as irrigants, under direct or video-assisted fiberoptic visualization.

Substantial Equivalence

Based on the indications for use statement and technological characteristics to the predicate devices, the ArthroCare Bipolar Loop Electrosurgery System has shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.

Summary of Safety and Effectiveness

The Bipolar Loop Electrosurgery System, as described in this 510(k), is substantially equivalent to the predicate device with respect to the indications for use and technological characteristics. The modification of the indications for use statement does not raise any new issues of safety or efficacy. There are no changes or modifications being made to the technology, principle of operation, materials, packaging and sterilization parameters that were previously cleared 510(k)s.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 9 2003

Ms. Valerie Defiesta-Ng
Director, Regulatory Affairs
ArthroCare Corporation
680 Vaqueros Avenue
SUNNYVALE CA 94085-2936

Re: K031029
Trade/Device Name: ArthroCare Bipolar Electrosurgery System, Model TBD
Regulation Number: 21 CFR §876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Codes: 78 FAS and KNS
Dated: March 31, 2003
Received: May 13, 2003

Dear Ms. Defiesta-Ng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

Device Name ArthroCare® Bipolar Loop Electrosurgery System

510(k) Number: K 031029

Indications for Use:

The ArthroCare Bipolar Loop Electrosurgery System is a bipolar electrosurgical device intended for use in patients requiring endoscopic surgery for general urological procedures. Urological tissue can be resected using this System, such as the prostate, in procedures including transurethral prostatectomy (TURP) and transurethral incisions in the prostate (TUIP), as well as tumors of the bladder wall. The System has been shown to be effective in tissue resection, ablation, and excision, as well as in hemostasis of blood vessels. It is intended for endoscopic procedures using saline solution, Ringer's lactate, or other conductive solutions as irrigants, under direct or video-assisted fiberoptic visualization.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use	X	OR	Over-the-Counter Use	____
(Per 21 CFR 801.109)				

David A. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K031029